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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,827	02/23/2004	Audrey VanStockum	SNH 3001	5450
7590 07/20/2006				
KRAMER & AMADO, P.C.				
Suite 240				
1725 Duke Street				
Alexandria, VA 22314				
		EXAMINER		
		ARNOLD, ERNST V		
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,827	VANSTOCKUM, AUDREY	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/04; 10/7/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/782,827 filed on 2/23/2004 and claims benefit of 60/449,866 filed on 02/27/2003.

In response to the restriction requirement, Applicant elected with traverse Group I claims 1-18, 21 and 22. Applicant asserted that the search required for the non-elected group would be co-extensive with that required for the elected group because both groups are directed to a method for treating disorders marked by a loss of pigmentation. The Examiner finds this persuasive and withdraws the restriction. Accordingly, claims 1-22 are pending in the application.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1616

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating vitiligo and gray hair, does not reasonably provide enablement for treating patients with any and all disorders marked by a loss of pigmentation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

Art Unit: 1616

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, a method of treating vitiligo and gray hair. However, Applicant is purporting to treat all disorders marked by a loss of pigmentation.

2) Nature of the invention

The nature of the invention is directed to a method of treating disorders marked by a loss of pigmentation.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like and laboratory technicians consisting of Masters level, Bachelors level and high school interns.

4) State of, or the amount of knowledge in, the prior art

The art teaches that treatment of vitiligo is difficult and includes exposure to UV light, oral medication and topical medications such as repigmenting agents, immunosuppressants and corticosteroid creams (MedlinePlus medical encyclopedia: vitiligo).

5) Level or degree of predictability, or a lack thereof, in the art

A high degree of unpredictability existed in the state of the prior art regarding how to treat disorders marked by a loss of pigmentation. Albinism is a result of the

Art Unit: 1616

body's inability to produce or distribute pigment because of one of several possible genetic defects (MedlinePlus medical encyclopedia: albinism).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a composition for a method of treating vitiligo and gray hair, it remains silent on the treatment of all other disorders.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method of treating all disorders marked by a loss of pigmentation.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the method and corresponding composition of the instant application does in fact treat all disorders marked by a loss of pigmentation.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the treatment of disorders marked by a loss of pigmentation, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method and

Art Unit: 1616

corresponding composition would actually treat all disorders marked by a loss of pigmentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 recites the limitation "...said female patient...". There is insufficient antecedent basis for this limitation in the claim. It appears that claim 20 should be dependent on claim 19. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montes (US 4,985,443) in view of Ortonne et al. (Vitiligo and Other Hypomelanoses of Hair and Skin, 1983), Kolyadenko et al. (International Journal of Artificial Organs 2000, 23(8), 568) and Kelly (Alternative Medicine Review 1997, 2(2), pages 116-127).

Applicant claims a method of treating disorders marked by a loss of pigmentation, comprising the steps of: a) administering an effective amount of vitamin B12 to a patient suffering from a loss of pigmentation; b) administering an effective amount of copper to said patient; c) administering an effective amount of folic acid to said patient; and d) administering an effective amount of vitamin C to said patient.

Determination of the scope and content of the prior art
(MPEP 2141.01)

Montes teach a method and composition for treating vitiligo consisting of oral administration of folic acid and vitamin C in capsules or tablets and intramuscular vitamin B12 (Abstract and claims 1-6).

Ortonne et al. teach that hypopigmentation of skin and hair seems to accompany copper deficiency in humans (page 102 bottom of page). Ortonne et al teach that addition of either copper or pantothenic acid restores normal pigmentation in depigmented rats (page 103, first paragraph). Ortonne et al. teach that reduced serum zinc levels have been noted in vitiligo (Page 236, bottom of page).

Art Unit: 1616

Kolyadenko et al. teach the application of copper and zinc containing adsorbents to the skin followed by UV irradiation in vitiligo treatment. It is the Examiner's position that the topical application teaching of Kolyadenko et al. suggests skin creams/lotions.

Kelly teaches that patients with vitiligo and achlorhydria experienced disappearance of vitiligo after starting HCl supplementation (Page 123, top left column).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Montes does not expressly teach claims a method of treating disorders marked by a loss of pigmentation, comprising administering an effective amount of: copper; pantothenic acid; hydrochloride salt; zinc; and UV irradiation to a patient suffering from a loss of pigmentation.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add administering an effective amount of: copper; pantothenic acid; hydrochloride salt; zinc; and UV irradiation to a patient suffering from a loss of pigmentation, as suggested by the combined teachings of Ortonne et al., Kolyadenko et al., and Kelly, in the method of Montes and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because "It is prima facie obvious to combine two compositions each of which is taught by the

Art Unit: 1616

prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It is the Examiner's position that one of ordinary skill in the art has the ability to administer the vitamin B12 in any of the known means such as intravenous, subcutaneous, sublingual, rectal, etc... It is the Examiner's position that one of ordinary skill in the art has the ability to compound the ingredients into a tablet as suggested by Montes (Claim 1) or a topical formulation as suggested by Kolyadenko et al.

In the absence of any unexpected results, the method of treating disorders marked by a loss of pigmentation is obvious whether administered to a female undergoing menses or not undergoing menses.

In the absence of any criticality/unexpected results, the presently claimed invention is considered *prima facie* obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

A prior art disclosure is not limited to its working examples or to its preferred embodiments. (*Merck & Co. Inc. v. Biocraft Labs. Inc.*, 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989); *In re Fracalossi* 681 F.2d 792, 794 n. 1, 215 USPQ 569,

Art Unit: 1616

570 n.1 (CCPA 1982); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); *In re Boe*, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1996).

Accordingly, the burden of proof is upon Applicants to show that the instantly claimed subject matter is different and unobvious over those taught by the prior art. (See: *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

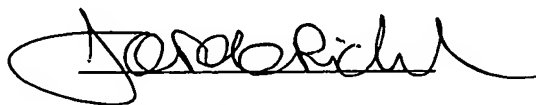
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
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Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann Richter', with a stylized, flowing script.

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